K112671

MAY - 4 2012

B. 510(k) SUMMARY (as required by 21 CFR 807.92)

Aesculap SterilContainer for
PreVac Steam, Immediate Use Steam, and EtO Sterilization
September 12, 2011

COMPANY:	Aesculap®, Inc. 3773 Corporate Parkway Center Valley, PA 18034 Establishment Registration Number: 2916714
CONTACT:	Denise R. Adams 610-984-9076 (phone) denise.adams@aesculap.com 610-791-6882 (fax)

TRADE NAME:	Aesculap SterilContainer
COMMON NAME:	Sterilization Container Wrap
CLASSIFICATION NAME:	Wrap, Sterilization
REGULATION NUMBER:	880.6850
PRODUCT CODE:	KCT

SUBSTANTIAL EQUIVALENCE

Aesculap, Inc. believes that the SterilContainer is substantially equivalent to:

- Aesculap PrimeLine Container (K073168)
- Aesculap SterilContainer System (Flash Indication) (K053389)
- Aesculap PriMed Rigid Container System (K944864)
- Aesculap Container System (K792558)

DEVICE DESCRIPTION

The Aesculap SterilContainer is designed as a container system that will allow for sterilization and storage of other medical devices. This system consists of full, three-quarter, half, quarter, extra long and wide body container sizes in various heights. There are a variety of accessories also available for this container system. They include mats, baskets, trays, holders, organizers, filters, indicator cards and tamper proof locks. This container is designed to be compatible for use in pre-vacuum steam, pre-vacuum immediate use steam and Ethylene Oxide (EtO) sterilization methods. The container bottom is made of anodized aluminum and has stainless steel handles on each end.

There are two types of lids for the container bottom. There are anodized aluminum lids that have removable retention plates to hold the filters in place. A stainless steel latch on each end of the lid lock the lid onto the container bottom. There are also PrimeLine lids available for use with the SterilContainer System. These lids are made from polyphenylsulfone commonly known

as Radel R. The PrimeLine lids have a reusable filter system. The reusable filter is PolyTetraFluorEthylene (PTFE). The PrimeLine lid, PTFE filter, and polypropylene filter are for Pre-vac steam and Immediate Use steam sterilization only.

INDICATIONS FOR USE

The Aesculap SterilContainer System is a reusable sterilization container system intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed device and also maintain sterility for 360 days. The SterilContainer System includes accessories such as mats, baskets, trays, holders, organizers, filters, indicator cards and tamper proof locks.
The container system consists of a three-quarter size, 8" tall perforated (JN744) or solid (JK744) aluminum bottom and a three-quarter size aluminum or PrimeLine lid. The lids are available in different colors to aide in set recognition. There are three types of filter materials. A single use paper filter (US751, US994), a single use polypropylene filter (MD344), and a reusable PTFE filter (JK090). The reusable PTFE is validated for 2200 uses. There are a variety of accessories for use with the container system. Please refer to the chart on the next page for sterilization compatibility of the container system.

Validated Sterilization Cycle Parameters

AAMI and AORN guidances recommend maximum load weights of 25 pounds or less in the healthcare setting.
360 days of event related shelf life testing has been conducted.

Sterilization Cycle Parameters	**PrimeLine Lid w/ JP050 filter**	**Aluminum Lid**	**Filter**	**Bottom**	**Max No. of Lumens/ Lumen Configuration**
Immediate Use (Non porous) 270°F Temp, 3 min. Exposure *Stacking not recommended*	JP011, JP012, JP013, JP014, JP015, JP016, JP017	JK785, JK786, JK787, JK788,JK789	US751 US994 MD344 JK090	JK744	
Immediate Use (Porous) 270°F Temp, 4 min. Exposure *Stacking not recommended*	JP011, JP012, JP013, JP014, JP015, JP016, JP017	JK785, JK786, JK787, JK788,JK789	US751 US994 MD344 JK090	JK744	1 lumen with ≥ 3mm I.D. x ≤ 400mm L and a second lumen ≥ 3.8mm I.D. x ≤ 370mm L
Pre-vacuum 270°F Temp, 4min.Exposure, 30 min. Dry time *Stacking should not exceed 18" in height*	JP011, JP012, JP013, JP014, JP015, JP016, JP017	JK785, JK786, JK787, JK788,JK789	US751 US994 MD344 JK090	JK744 JN744	1 lumen with ≥ 3mm I.D. x ≤ 400mm L and a second lumen ≥ 3.8mm I.D. x ≤ 370mm L
Ethylene Oxide 130° F temp, 60 min exposure ≥ 50% Relative Humidity 725 mg/L gas pressure *Stacking not recommended*		JK785, JK786, JK787, JK788,JK789	US751 US994	JK744 JN744	1 lumen with ≥ 3mm I.D. x ≤ 400mm L and a second lumen ≥ 3.8mm I.D. x ≤ 370mm L

Accessories	Pre-vac Steam	Immediate Use Steam	EtO
Stainless Steel baskets, basket lids and dividers	X	X	X
Instrument Organization System (Silicone and Stainless Steel racks, brackets, holders, and clamps)	X	X	X
Silicone mats	X	X	X
Stainless Steel racks, trays, holders, clamps, brackets and platforms	X	X	X

TECHNOLIGICAL CHARACTERISTICS(compared to predicate(s))

The Aesculap SterilContainer is compatible for use in pre-vacuum steam, pre-vacuum immediate use steam and EtO. These SterilContainers are a similar shape and size as the predicate devices. The material used is the same as that used to manufacture the predicate devices. The new three-quarter size eight inch (187mm) container is exactly the same as the SterilContainers that received clearance in K944864, K053389, and K073168 with the exception of its size. This container represents the worst case vent to volume ratio for the SterilContainer System.

Device/ System	Aesculap SterilContainer w/ Aluminum Lid and *PrimeLine Lid	Aesculap PrimeLine Container	Aesculap SterilContainer (Flash)	Aesculap PriMed Rigid Container System	Aesculap Container System
510(k)	K112671	K073168	K053389	K944864	K792558
Sterilization Processes	Pre-vac steam, Immediate Use Pre-vac steam & EtO	Pre-vac steam, Immediate Use Pre-vac steam	Immediate Use steam	Gravity steam, High-vacuum steam, EtO	Pre-vac steam, EtO
Material	Anodized Aluminum/Radel R	Anodized Aluminum/Radel R	Anodized Aluminum	Anodized Aluminum/ JADEX	Anodized Aluminum
Worst case Vent to Volume Ratio	.41	.49	.68	.59	Not available
Filter	Single use paper filter, *single use polypropylene filter, *reusable filter	Reusable filter	Single use paper filter	Single use paper filter	Single use paper filter, reusable filter
Shelf-life/ Barrier	360 days (event related)	360 days (event related)	N/A	Not defined	Not defined
Reuse testing	100 cycles minimum	100 cycles minimum (bottom)/ 2,200 cycles (lid)	100 cycles minimum	100 cycles minimum	100 cycles minimum
Max total weight	25 pounds	35 pounds	35 pounds	25 pounds	35 pounds

*The PrimeLine lid, polypropylene fiter, and the reusable filter are not for use in EtO sterilization

PERFORMANCE DATA

All required testing per "Draft Guidance for the Preparation of Premarket Notifications 510(k)'s" for Aesculap SterilContainer was completed on this new three-quarter size 8" (187mm) container which has the worst case vent to volume ratio of the SterilContainer System making this container the most challenging container to achieve sterilization. The Aesculap SterilContainer was fully validated for pre-vacuum steam, pre-vacuum immediate use steam, and EtO sterilization processes. These validations were conducted in accordance with FDA guidance and available AAMI standards by a qualified testing laboratory. This performance testing demonstrates substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Denise Adams
Regulatory Affairs Specialist
Aesculap, Inc.
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

MAY - 4 2012

Re: K112671
Trade/Device Name: Aesculap SterilContainer System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: April 23, 2012
Received: April 25, 2012

Dear Ms. Adams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K112671

Device Name: ***Aesculap SterilContainer System***

Indications for Use:

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Prescription Use _____ and/or Over-the-Counter Use X

(per 21 CFR 801 Subpart D) (per 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claxton -W

(Division Sign-Off)

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K112671